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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,594	11/01/1999	JEFFERY J. WHEELER	16303-002430	8936

7590

03/25/2003

WILLIAM B KEZER
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 941113834

EXAMINER

EPPS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/25/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/431,594

Applicant(s)

WHEELER ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42 and 44-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42 and 44-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-22-02 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

3. Applicants have not responded to the objections to the Drawings set forth in the PTO-948 attached to the Official Action mailed 8-09-2001. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Response to Amendment

4. The Declaration under 37 CFR 1.132 filed 10-25-02 is insufficient to overcome the rejection of claims 42 and 44-75 based upon a rejection under 35 USC 102(e) as set forth in the last Office action because the declaration fails to set forth facts regarding this rejection, and the facts presented are not germane to the rejection at issue. For example, the Hope Declaration states that claims 42 is drawn to "[A] method of introducing a nucleic acid into a cell, said

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method comprising contacting said cell with a nucleic acid-lipid particle comprising a cationic lipid, a conjugated lipid that inhibits aggregation of particles, and a nucleic acid, wherein said nucleic acid in said nucleic acid particle is resistant in aqueous solution to degradation with a nuclease.” However, contrary to the Hope Declaration, claim 42 of the instant application is not drawn to a method, but is drawn to “[A] nucleic acid-lipid particle for introducing a nucleic acid into a cell, said particle comprising a cationic lipid, a conjugated lipid that inhibits aggregation of particles, and a nucleic acid, wherein said nucleic acid in said particle is resistant in aqueous solution to degradation with a nuclease.”

Moreover, the Hope Declaration makes mention of the teachings of the specification for making lipid-nucleic acid particles via novel, hydrophobic nucleic-acid lipid intermediate complexes. However, it is noted that the instant claims are drawn to “a nucleic acid-lipid particle” and does not incorporate the novel method for making nucleic acid lipid particles disclosed in the specification as filed.

Additionally, the Hope Declaration opines that the method of encapsulation taught by Choi et al. in Example 9 would not result in the nucleic acid-lipid particles of the present invention. However, the Declaration provides no scientific rationale to support this conclusion. Moreover, it is noted that the encapsulation of Example 9 does not teach a method for encapsulation of nucleic acid, it describes a method for encapsulating the drug vincristine. Therefore, it is unclear how any conclusions can be drawn regarding the utility of this method for encapsulation of nucleic acid.

Finally, the Hope Declaration concludes, “in my opinion, the Choi et al. patent does not teach (or even suggest) the method recited in claims 42 and 44-71 because Choi et al. do not

teach (or even suggest)(1) nucleic acid-lipid particles, wherein the nucleic acid in the nucleic-acid lipid particles is resistant in aqueous solution to degradation with a nuclease, or (2) methods for making such nucleic acid-lipid particles." However, it is noted that the instant claims are drawn to a product, and not to a method for the synthesis of the claimed product. Additionally, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the liposomal particles of Choi et al. made from PEG-Ceramide lipids are disclosed as being "less susceptible to hydrolysis, they have a prolonged half-life resulting in prolonged circulation. Additionally, the liposome pharmaceutical composition can include lipid-protective agents that protect the liposomes against free-radical and lipid-peroxidative damage upon storage. Such protective agents include alpha-tocopherol and water-soluble, iron-specific chelators, such as ferrioxamine. (See col. 17, lines 54-62)"

The Hope Declaration does not provide any evidence of unexpected results that would suggest that the particles synthesized by the methods taught in the specification are unobviously distinct from the liposomal compounds of Choi et al. As stated in the prior Office Action, "[p]roducts of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

5. Claims 42, and 44-75 remain rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al. for the reasons of record set forth in the Official Action mailed 5-16-02.

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Applicant's arguments filed 10-22-02 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the prior art reference does not disclose each and every aspect of the claimed invention as amended. In particular, Applicants argue that the Choi et al. reference does not teach wherein the nucleic acid in the particles of instant invention is resistant in aqueous solution to degradation with a nuclease. Moreover, Applicants provide a Declaration filed under 37 CFR 1.132 by Michael J. Hope. The Hope Declaration is insufficient to overcome the pending rejection of claims 42 and 44-75 over Choi et al. under 35 USC 102(e) for the reasons set forth above.

Conclusion

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

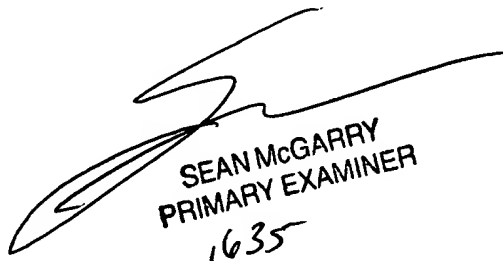
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
March 21, 2003


SEAN McGARRY
PRIMARY EXAMINER
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